

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO**

“O” COMPANY, INC., HEALTH DELIVERY SYSTEMS,
INC., WORLD DENTAL IMPLANTS, INC., and
DAVID DALISE, D.D.S., individually and as
President of “O” COMPANY, INC., HEALTH
DELIVERY SYSTEMS, INC., and
WORLD DENTAL IMPLANTS, INC.,

Plaintiffs,

vs.

No. CIV 98-981 M/KBM

OSTEOTECH, INC., d/b/a CAM IMPLANTS,
INC.,

Defendants.

MEMORANDUM OPINION AND ORDER

THIS MATTER comes before me on Cross Motions for Summary Judgment filed by Defendant Osteotech, Inc. and by Plaintiffs “O” Company, Inc., Health Delivery Systems, Inc., World Dental Implants, Inc. and David Dalise, D.D.S. Having reviewed the cross motions, the responses and replies, the numerous attachments to both motions and well as the other pleadings filed in this case, I find that both Motions for Summary Judgment will be denied. Neither Plaintiffs nor Defendant is entitled to Summary Judgment because there are disputed material issues of fact present.

FACTUAL BACKGROUND

The Plaintiff David Dalise, D.D.S., is the president of the other three plaintiff companies, “O” Company, Inc., Health Delivery Systems, Inc. and World Dental Implants. Dr. Dalise is an dental implantologist and his three companies are or were in the business of dental implantology. “O” Company, Inc. designed and manufactured dental implant devices while Health Delivery Systems, Inc., World Dental Implants, Inc. and Dr. Dalise purchased the implants and either sold them to other implantologists or used them in a dental implant practice.

Dental implants are metal substitutes for real teeth and consist of several components. The base of the dental implant, which is metal, needs to be coated with a specific substance so that the base will bond with the human bone when implanted. Defendant Osteotech, Inc. is a developer and marketer of implant products for surgery. As part of this business, it provided coating services to dental implant customers. In this case Osteotech provided hydroxylapatite (HA) coatings through its subsidiary companies, CAM Implants b.v. and CAM Implants, Inc., applying the HA coating to the base of the implants which Osteotech received from the Plaintiffs. The HA coatings were sprayed on the implants with a plasma-spray gun. The implants were then returned to the Plaintiffs to be used by Plaintiffs for implantation or sold to other dentists for implantation in patients.

Plaintiffs began sending their dental implants in 1990 to CAM bv, a Netherlands corporation, to be coated with the HA coating. CAM Implants, Inc., a U.S. corporation, was formed in 1991 and started operations in Arvada, Colorado. Thereafter Plaintiffs began sending their implants to CAM Implants, Inc. for coating. CAM bv and CAM Implants, Inc. were acquired by Osteotech in approximately June, 1992. Plaintiffs continued to purchase HA coating

services from the subsidiary companies of Osteotech until the end of 1992.

In 1991, Plaintiffs began observing a number of dental implant failures in their dental implant practice. Plaintiffs also began receiving complaints from their customers about dental implant failures they were experiencing. Dental implants are a Class III critical medical device, regulated by the FDA. Pursuant to FDA guidelines for the investigation of failed implants, Plaintiffs began investigating each step of the implant process. There were fifteen possible causes of implant failure. The failure of the HA coating was one possible cause.

Plaintiffs and Osteotech began communicating about the failures. The crystallinity levels of the HA coating had been an issue discussed previously by the parties. Concerned about the crystallinity levels in the coatings, Plaintiffs hired an independent materials testing company to run tests on the HA coatings. The tests showed that the crystallinity levels on the HA coatings were in accordance with FDA regulations. Dr. Dalise sent a letter dated June 28, 1993 to Osteotech regarding the implant failures and the coating provided by the Defendant. Osteotech also had testing done on its HA coating and sent the resulting report to Plaintiffs. The conclusion of that report was that the HA coatings were not defective.

Dr. Dalise changed his implant procedure including incorporating a mechanical design change which placed the implant base deeper into the bone. The complaints from Plaintiffs' customers and patients about implant failures declined. Plaintiffs also began using a different implant coating service in early 1993. Plaintiffs have presented several, contradictory reasons for choosing a different HA coating company. Meanwhile however, Plaintiffs were experiencing such financial difficulties that Dalise, "O" Company and Health Delivery Systems, Inc. filed Chapter 11 bankruptcies.

In 1997, Plaintiffs began receiving reports of implant failures accompanied by serious dental health problems - large lesions in the jaw, inflammation and infection. In the course of its investigation into the failures, Plaintiffs had the CAM HA coatings tested by Bio-Coat, Inc., another provider of HA coatings for dental implants. Bio-Coat concluded that the CAM coatings had not been melted properly leaving porosity which in turn led to the implant failures. Plaintiffs filed this lawsuit on July 16, 1998, several months after receiving the Bio-Coat report, alleging causes of action in warranty and fraud. Defendant Osteotech vehemently denies that its HA coating or any of its coating procedures were defective or are the cause of any of the implant failures.

SUMMARY JUDGMENT

Summary judgment is an integral part of the Federal Rules of Civil Procedure which are intended to “secure the just, speedy and inexpensive determination of every action’.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) (quoting Fed. R. Civ. P. 1). Under Rule 56(c), summary judgment is appropriate when the court, viewing the record in the light most favorable to the non-moving party, determines that “there is no genuine dispute over a material fact and the moving party is entitled to judgment as a matter of law.” *Thrasher v. B & B Chemical Co.*, 2 F.3d 995, 996 (10th Cir. 1993) (quoting *Russillo v. Scarborough*, 935 F. 2d 1167, 1170 (10th Cir. 1991).

The movant bears the initial burden of showing “there is an absence of evidence to support the nonmoving party’s case.” *Bacchus Indus., Inc. v. Arvin Indus., Inc.*, 939 F. 2d 887, 891 (10th Cir. 1991). Once the movant meets this burden, Rule 56 (e) “requires the nonmoving party

to go beyond the pleadings and by her own affidavits, or by the ‘depositions, answers to interrogatories and admissions on file’, designate ‘specific facts showing that there is a genuine issue for trial.’” *Celotex*, 477 U.S. at 324. “Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no ‘genuine issue for trial.’” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

In this case there are cross motions for summary judgment on the issue of the statute of limitations, each side claiming that there are no material issues of fact in dispute and that each is entitled to judgment as a matter of law. I find, however, that there are numerous, disputed material issues of fact regarding the issue of the statute of limitations and alleged fraudulent concealment. These material issues of fact preclude both motions for summary judgment.

DISCUSSION

Counts III and IV allege a breach of express and implied warranties and are governed by New Mexico’s four year statute of limitations. N. M. Stat. Ann. §55-2-725 (Repl. Pamp.1993) The cause of action accrues when the breach of warranty is or should have been discovered. *Id.* Counts V, VI and VII, which allege claims of fraud, misrepresentation and Unfair Trade Practices Act, are also governed by a four year statute of limitations. N. M. Stat. Ann. §37-1-4 (Repl. Pamp. 1990). The cause of action accrues under these claims when the injured party knew or by the exercise of reasonable diligence should have discovered the defect or the cause of injury. *Sawtell v. E.I. Dupont de Nemours & Co.*, 22 F.3d 248, 251 (10th Cir. 1994), *cert. denied*, 513 U.S. 917 (1994).

Defendant argues that the alleged defect or breach of warranty was discovered when the

first failed implants began occurring in 1991 and in no event, not later than the letter of June 28, 1993 which Dr. Dalise wrote to Osteotech. In the alternative, Defendant points to the July 17, 1995 letter Dr. Dalise wrote to Jeffries as undisputed evidence that Plaintiffs knew of or should have discovered an alleged defect in the HA coating as a result of the reports of failed implants from 1991 to 1993. Similarly, Defendant points to the November 24, 1999 Affidavit of Dr. Dalise as evidence that Plaintiffs knew of or with reasonable diligence should have discovered the alleged defect in the HA coatings no later than June, 1993. See, e.g. *Sawtell v. Du Pont de Nemours & Co.*, 22 F. 3d 248 (10th Cir. 1994), *cert. denied*, 513 U.S. 917 (1994). Defendant has argued that these documents are uncontroverted evidence that the statute of limitations for this lawsuit began to run no later than 1993 and that therefore this suit is time barred.

However, I find the letters and affidavit are not dispositive of the issue of when Plaintiffs' acquired their knowledge of an alleged defect in the Defendant's product or the issue of when, with reasonable diligence, these particular Plaintiffs should have discovered an alleged defect in the HA coating sufficient to begin the running of the statute of limitations. All of these documents have been thoroughly and exhaustively analyzed by both parties and the arguments and various interpretations do not need to be repeated here. What I do find is that the documents are not conclusive in and of themselves on the issues regarding the application of the statute of limitations. The letters and affidavit present specific material issues of fact - what the Plaintiffs knew regarding an alleged defect in the Defendant's product, when they acquired this knowledge, and when, or if, by the exercise of reasonable diligence, Plaintiffs should have discovered the alleged defect in Defendant's product - all of which need to be decided by a fact finder.

Osteotech also argues that the Complaint's allegations are an admission that Plaintiff knew

of an alleged defect in the Defendant's product. Paragraph 15 of the Complaint states that "[s]ince 1991, numerous reports of implant failure have been reported. The implants failed because the coating was not applied properly by the Defendant to the implants." Paragraph 16 states "Plaintiffs had noticed the coating was stripped off of the failed implants." Without more however, I do not find that these allegations necessarily mean, as Defendant has argued, that since 1991 Plaintiffs knew the implants failed because the coating was not properly applied. The facts alleged in the Complaint, that Plaintiffs had noticed that the coating was stripped off of the failed implants, go to the issue of when the Plaintiffs should have discovered, with the exercise of reasonable diligence, the alleged defect. Again, that is a factual issue which will need to be decided by a fact finder.

Lastly, Plaintiffs have argued that they could not have discovered, even by the exercise of reasonable diligence, the alleged defect in the Defendant's product because of fraudulent concealment by the Defendant and that therefore the statute of limitations is tolled during the pendency of the fraudulent concealment. To demonstrate fraudulent concealment the Plaintiffs must show:

- (1) the use of fraudulent means by the party who raises the bar of the statute; (2) successful concealment from the injured party; and (3) that the party claiming fraudulent concealment did not know or by the exercise of reasonable diligence could not have known that he might have a cause of action.

Continental Potash v. Freeport-McMoran, Inc., 115 N.M. 690, 698, 858 P.2d 66, 71 (1993), *cert. denied*, 510 U.S. 116 (1994). Plaintiffs have cited to evidence in their Cross Motion and Memorandum which they claim supports the three requirements of a fraudulent concealment claim. The elements of the claim are vigorously disputed by the Defendant who argue that

Plaintiffs have failed even to offer any credible evidence in support of this claim.

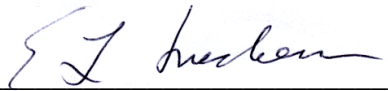
I find that the evidence cited by the Plaintiffs in support of the elements of the claim of fraudulent concealment and the evidence presented by the Defendant to prove that there was no fraudulent concealment is very much disputed and not at all conclusive of either argument. A fact finder needs to hear the evidence presented by both sides on the issue of fraudulent concealment and determine whether there was any fraudulent concealment. I cannot grant summary judgment for either the Plaintiffs or the Defendant on this issue at this stage of the lawsuit.

The parties to this lawsuit, and the attorneys representing them, are vigorously contesting the issues, not only the factual and legal issues brought forth in these summary judgment motions but also numerous issues brought forth previously in the course of discovery. While zealous advocacy is to be commended, at times the contentiousness in this lawsuit seems to be unnecessary for the purpose of resolving this dispute. Now that I have denied the Cross Motions for Summary Judgment on the grounds that material issues of fact are in dispute, discovery will begin again. The additional discovery necessary to go to trial should not take long and should not be unnecessarily burdensome on either party. A just, speedy and inexpensive determination of this dispute will not only comport with the Federal Rules of Civil Procedure but would be in the best interest of all involved.

CONCLUSION

The Defendant Osteotech, Inc.'s Motion for Summary Judgment is DENIED. Plaintiffs' "O" Company, Inc., Health Delivery Systems, Inc., World Dental Implants, Inc. and David Dalise, D.D.S. Cross Motion for Summary is DENIED. The Motion and Cross Motion for Summary

Judgment are denied because there are material issues of fact in dispute. Neither party is entitled to judgment on the issues of the statute of limitations or fraudulent concealment as a matter of law at this time.



SENIOR UNITED STATES JUDGE